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IN THE
Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC. *et al.*,
Petitioners,

v.

IVES LABORATORIES, INC.,
Respondent.

BRIEF FOR MEDICINE IN THE PUBLIC INTEREST AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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BRIEF FOR MEDICINE IN THE PUBLIC INTEREST AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

I. AUTHORITY TO FILE

This Amicus Brief is presented to the Court under Rule 36.2 and letters of consent from the Petitioners and Respondent have been filed with the Clerk of the Court.

II. INTEREST OF AMICUS CURIAE

Medicine in the Public Interest, Inc. (MIPI) is a non-profit, tax exempt corporation organized in the early 1970s for the purpose of conducting studies, performing analyses, and making evaluations of public and private programs and policies affecting health care in the United States.

Through an interdisciplinary approach, reflecting governmental, academic, medical, industrial, and consumer interests, MIPI has acted as a forum for these disparate interests to identify common ground for dealing with the complex issues

involved in drug research and development, review and approval, distribution and related areas. The results of these efforts have yielded several publications,[1] distributed to policy makers and other interested parties throughout the United States.

One of MIPI's publications — *Medical, Legal, and Economic Aspects of Drug Product Selection* (1979) — is particularly relevant to the case before this Court.[2] MIPI's interest and expertise in issues related to drug policy and its concern for the rights and interests of patients affected by such policy led MIPI to bring to this Court's attention, as it interprets the pending trademark and competiton law issues, the need to consider the effects on those most vulnerable to deception and confusion in drug substitution and dispensing — the patient/consumer.[3]

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[1] *Rights and Responsibilities in Drug Research* (1977); *Postmarking Surveillance of Drugs* (1977); *Drug Abuse, Data Systems, and Regulatory Decisions* (1978)

[2] Copies of this publication have been lodged with the Clerk of the Court. See pages 31-34 which contain a discussion of disclosure, informed consent, and "look-alike" drugs. See also the statement of the Food and Drug Administration representative, pages 57-58, which "favor[s] consumers' knowing at all times whenever they have received a substituted product, regardless of how innocuous the drug might be."

[3] MIPI notes the submission of an amicus brief by the American Association of Retired Persons purporting to represent the public interest or at least a portion of it, namely the elderly. In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), AARP also filed an amicus brief. AARP relates in its *Virginia* brief that it operates walk-in pharmacies and is "the largest non-governmental mail order dispenser of prescription drugs," Brief at 2. Thus, AARP has an interest in the present case both on behalf of the elderly and as one of the largest pharmacies. Those interests are frequently mutually exclusive as seen in this case and discussed in MIPI's brief. Furthermore, AARP based on its argument in the *Virginia* brief on the consumers' "right to know," Brief at 6. It is interesting that AARP makes no mention of that right in the present case. Instead, it is MIPI alone that advocates that the public interest is best served by providing patient/consumers, including the elderly, with full disclosure to enable them to exercise their right of informed consent.

III. SUMMARY OF ARGUMENT

Although the issues and arguments before this Court focus on federal trademark law and its effect on competition in the marketing of ethical pharmaceuticals, it is imperative that the rights and interests of the *patient* be fully protected in accordance with the long-established legal principles of full disclosure and informed consent whenever medical professionals — physicians *and pharmacists* — prescribe and dispense a drug. Furthermore, such disclosure guarantees that the patient, as a *consumer*, receives the cost savings to which he is entitled when generic substitution occurs.

Petitioners would have this Court sanction the dispening of substituted drugs without disclosure to the patient and without the patient's corresponding informed consent, essentially on the grounds that anxiety may result if the patient be well informed. This paternalistic approach not only is outmoded, but contradicts the consistent position of the Congress, federal regulatory agencies, and federal courts that informed consent and disclosure to the patient are the cornerstone of the patient-physician/pharmacist relationship. Exceptions for the sake of convenience or speculative concerns about patient anxiety cannot be countenanced as a matter of fact and law.

The patient/consumer must be provided with full disclosure to permit the making of an informed decision as it affects his health interests. Disclosure is also necessary as it affects the resolution of potential products liability claims, as well as the removal of drugs that pose potential health hazards.

The question before the court is not one of economics between generic and brand-name manufacturers. Rather, the fundamental issue is whether patient/consumers will be deprived of protection offered through the time honored mechanism of informed consent and whether they will be deprived of the savings realized from generic substitution. Full disclosure by the physician about the prescribed drug and by the pharmacist,

who in his professional judgment substitutes a generic product, is an absolute, positive, legal obligation to the patient. It cannot be defeated by permitting the use of look-alike drugs to keep the patient/consumer blithely unaware of what has transpired.

MIPI, in its *Drug Product Selection* report referred to previously, summarized the applicable standard at page 2:

> Drug-product selection involves a body of ethical and legal consumer rights. These rights include knowledge that substitution has occurred and an ability to make informed choices about drug products based on information provided by both physicians and pharmacists. *Consumer deception should not be promoted or practiced for any reason.* (Emphasis added).

Petitioners' explicit claim that look-alike drugs are designed to deceive the patient clearly violates this principle. Despite all claims about functionality of color and other technical arguments, the fact remains that the use of the look-alike drugs promotes deception of the patient/consumer in violation of clearly established principles designed to protect him. The tenuous claim of functionality of color cannot be allowed to defeat the patient's right to know and, in turn, enable him to exercise his informed consent.

IV. ARGUMENT

A. The Right To Full Disclosure And Informed Consent Requires That Patient/Consumers Realize That Drugs Being Dispensed Are Generic Substitutes

The consumer's right to know, embodied in the field of medicine by the concept of informed consent, is a long standing principle of American law. This principle is directly applicable to the present case. Petitioners' production and marketing of generic pharmaceuticals so similar in appearance to brand-name products already on the market is a deliberate attempt to mislead the American consumer, and preclude the American patient from exercising his right of informed consent. The

process of generic drug substitution gives consumers a choice and that choice should not be thwarted by pharmaceutical products identical or so nearly identical in appearance that consumers cannot distinguish between them.

In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), this Court found

> So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. *It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed.* To this end, the free flow of commercial information is indispensable.

425 U.S. at 764 (Emphasis added). Intelligent and well informed decisions on drug purchases can be made by consumers only if they realize and understand that they are receiving a generic substitute.

The concepts of informed consent and right to know have been traditionally applied where a patient is receiving medical care. The concepts have developed over the years to the point where patients today have a right to be told and to understand the medical process to which they are to be subjected. *See, Cunningham* v. *Yankton Clinic*, 262 N.W.2d 508 (S.D. 1978) for a development of the informed consent doctrine. These concepts have consistently been noted and accepted without question, *Rush* v. *Miller*, 648 F.2d 1075, 1076 (6th Cir. 1981); *Lambert* v. *Park*, 597 F.2d 236, 238-239 (10th Cir. 1979); *Henderson* v. *Milolsky*, 595 F.2d 654, 656-657 (D.C. Cir 1978); *Dewes* v. *Indian Health Service*, 504 F.Supp. 203, 206-207 (D.S.D. 1980); *Margaret S.* v. *Edwards*, 488 F.Supp. 181, 206-208 (E.D. La. 1980) and *Hitchcock* v. *United States*, 479 F.Supp. 65, 78 (D.D.C. 1979).

Similar requirements are mandated by a variety of Federal regulations, including those for human experimentation gener-

ally and drug testing in humans specifically. The regulations of both the Department of Health and Human Services, 45 CFR 46, and of the Food and Drug Administration, 21 CFR 50 *et seq.*, strongly mandate that all human subjects be fully informed before they make any decisions affecting their medical future. The principles of informed consent developed in research settings are equally applicable to medical practice. *See* R. Levine, M.D., *Ethics and Regulation of Clinical Research* (1981), at 93-95. It is inconceivable that Petitioners argue for a lesser standard for the dispensing of drugs to patient/consumers.

B. Patient/Consumers Are Not Being Informed That Generic Substitutes Are Being Dispensed By Pharmacists

The record in this case is replete with examples of mislabeling by pharmacists filling prescriptions with generic cyclandelate. The opinion of the Second Circuit in the case below noted that an impartial test shopping demonstrated that 29% of the pharmacists shopped mislabeled generic cyclandelate as Cyclospasmol, *Ives Laboratories* v. *Darby Drug Co.*, 638 F.2d 538, 453 (2nd Cir. 1981). It is reasonable to assume that pharmacists, who either intentionally or mistakenly mislabel generics as brand-names, are unlikely to disclose the fact that a generic has been substituted for the prescribed drug.

Passing off generic look-alike substitutes as brand-name pharmaceuticals, either intentionally or inadvertantly, is not limited to this case. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3rd Cir. 1980), the Third Circuit recounted a study showing a 4% unlawful substitution rate and a 23% illegal mislabeling rate for two other drugs, 625 F.2d at 1059. *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157, 158 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 766 (3rd Cir. 1978) likewise noted widespread passing off and in *Hoffmann-LaRoche Inc.* v. *Premo Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980)

the District Court calculated that mislabeling occurred 43% of the time in a field study, 210 U.S.P.Q. at 380.

In *Pennwalt* v. *Zenith Laboratories, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979), the court wrote:

> If, as a practical matter, substitutions cannot be detected, it is a short step from passing the savings on to the consumer to passing the savings on to oneself.

472 F.Supp. at 420. The District Court found examples of pharmacists doing just that. The clear, obvious, most effective way to prevent such chicanery is to require that both brand-name drugs and generic substitutes have readily apparent and distinguishable appearances.

A recent survey found that 23% of the time (67 out of 238) pharmacists either failed to properly substitute generic drugs or dispensed generic drugs but charged the same or higher prices as the comparable brand-name drugs, *Report of [New York State] Attorney General Robert Abrams and [New York City] Consumer Affairs Commissioner Bruce Ratner on New York Generic Substitution Law* (1979), p.10.

These results confirmed those of an earlier New York study which found that of thirty pharmacists, randomly surveyed, thirteen violated the New York substitution law. This "mistake rate" of 43% no doubt influenced the directors of the study who noted that "the study shows that comparison shopping is essential to obtain prescription drugs most economically." The New York City Department of Consumer Affairs, *Comparative Drug Prices and Compliance with the Generic Drug Substitution Law in New York City: An Empirical Study* (1978), pp. 2, 5-7. Comparison shopping can be done only if patients can distinguish between products and can make an informed decision as to which they wish to purchase.

It is unrealistic to expect consumers to inquire about the availability or prices of substitutes if they have no idea that

substitutes are available or are being dispensed. Many patients are unaware of substitution laws in general or may not realize they are applicable to a particular prescription. In 1979, the Federal Trade Commission's Bureau of Consumer Protection published a staff report, *Drug Product Selection*, that focused on generic substitution laws. The report noted that substitution laws in general envisioned patient participation and decision-making but that some consumers were unaware of substitution laws, at 168, 191. The FTC report contained the "Model Drug Product Selection Act" which included a requirement that consumers be notified by pharmacists when substitution occurs and be told of their right to refuse the generic substitute, at 279.

Consumers are entitled to be informed by pharmacists that a substitute is being dispensed in order that they may make an intelligent, informed choice, since

> Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely at the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision.

Canterbury v. *Spence*, 464 F.2d 722, 783, n.36, (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). The requirement that pharmacists disclose substitution, coupled with a ruling that generics be unambiguously distinguishable in appearance from the brand-name product, will guarantee achievement of the goals of (1) substitution to foster savings for consumers, and (2) informed consent to protect patients.

Of further concern to consumers is the practice of some pharmacists to provide generic substitutes when the physician has specified that the brand-name drug be provided. The record demonstrates instances of such conduct and the Second Circuit noted undisputed evidence "suggesting that illegal substitution and mislabeling in New York are neither de minimus nor inadvertent," 638 F.2d at 544. The Second Circuit was no doubt

influenced by Respondent's evidence of fifteen instances of illegal substitution of generic cyclandelate for Cyclospasmol, *Id.* at 543, and the six New York City indictments for the same offense, *Id.* at 544.

The fact that disclosure is not being made is attributable not only to pharmacists but also to Petitioners' use of visually identical products. The Second Circuit properly held that generic manufacturers may not provide the means to encourage deception where they could "reasonably anticipate" that deception would occur, 638 F.2d at 543. This holding is fully consistent with traditional interpretations of trademark law. As this Court stated long ago:

> A man is not to sell his own goods under the pretense that they are the goods of another man; he cannot be permitted to practice such a deception, *nor to use the means which contribute to that end.*

Hanover Star Milling Co. v. *Metcalf,* 240 U.S. 403, 413-414 (1916) (Emphasis added).

C. Petitioners' Use Of "Look-Alikes" Is Designed To Deceive Patient/Consumers To The Detriment Of Their Legitimate Economic And Health Interests

Petitioners have deliberately attempted to mislead the American public. They readily admit that they intend their products to be identical, or nearly identical, in appearance as Cyclospasmol. The distinctive color of Cyclospasmol was not determined by the raw materials, but rather was chosen by the manufacturer. Petitioners have marketed their generic cyclandelate with identical colors, even though there was nothing to prevent them from choosing a myriad of other colors to distinctly identify their own generic products.

Petitioners originally did not even mark their capsules with their name or identification number but rather left them blank, thereby further adding to the confusion and misidentification.

Since this action was initiated, two of the Petitioners, Premo and Inwood, have begun to label capsules with their identification. *See* the Second Circuit opinion, 638 F.2d at 540, n.4. However, drug identification names and numbers are imprinted in very small type. It is totally unrealistic to expect patient/consumers to differentiate between apparently identical products on the basis of some very "fine print" on the capsule.

Furthermore, in perhaps the most glaring example of deception, one of the Petitioners, Sherry Laboratories, originally marketed its generic cyclandelate as Spasmol, an obvious attempt to capitalize on Respondent's trade name Cyclospasmol. This is but the most extreme example of a consistent, continued attempt by Petitioners to deny the American consumer the right to make an informed decision as to which pharmaceutical product to purchase and which to ingest pursuant to a prescribed medical regimen.

Such activities by some of the Petitioners are not limited to the cyclandelates involved in this case. Prior activities by some of the Petitioners have left a trail of deliberate confusion, copying of pre-existing products, and patent infringement. *See, e.g., SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* and cases cited therein, 625 F.2d at 1058, n.1; *A.H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015 (E.D.Mo. 1980) (Petitioner Inwood Laboratories); and *Hoffmann-LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc., supra,* and cases cited therein, 210 U.S.P.Q. at 378.

Petitioners' justification for deceiving the consumer is based on an outmoded, paternalistic theory that the consumer is actually better off being deceived. Petitioners argue that patients receiving generic drugs different in appearance from brand-names that they have been using would refuse to take the generics. Petitioners attempt to paint a sorry picture of bewildered patients, anxious consumers, all unable to grasp the simple fact that the equivalent pharmaceutical ingredients may

be contained in different color capsules. Petitioners appear to suggest that the elderly, all of whom Petitioners appear to assume are in advanced stages of senility, are particularly prone to confusion and anxiety and would refuse to take a different colored drug.

American consumers, especially those over sixty, are not the fools Petitioners would have this Court believe. The consumers of this country are fully capable of understanding that the same product may come in different packages and are able to make informed, reasoned decisions as to which product they wish to purchase, based on their confidence in the manufacturer and on the price of the product. The notion that the elderly are unable to make informed medical decisions has been repeatedly rejected by leading authorities and studies. For a review of such authority see Ostfeld, "Older Research Subjects: Not Homogenous, Not Especially Vulnerable," *IRB: A Review of Human Subjects Research*, Vol. II, No. 8 (1980), at 7, and "National Institute on Aging: Protection of Elderly Research Subjects", DHEW Publication 79-1801 (1979).

If indeed some patients do not take their medicine regularly, there are many factors affecting compliance, the least of which is the color, size, or shape of the capsule. The key factor in patient compliance is the doctor-patient relationship supplemented by the pharmacist-patient relationship. A patient who is informed, knowledgeable and encouraged to take medicine will do so regardless of the appearance of the pill if he believes it is in his best medical interest. The frequency of medication and the number of drugs may also affect compliance, but again the crucial element is explanation by the physician or pharmacist, not deception or confusion by the color, size, or shape of the capsules or tablets involved.

Similarly, the condition of the patient may affect compliance. Sick patients obviously have more problems in complying than relatively healthy ones. Both costs and confidence

in the medication can determine whether drugs are purchased and then used. The cost factor problem can be reduced by identifying generics so that the consumers will know they are getting substitutes and accordingly can shop for and demand the best price.

The Petitioners' justification for identically-colored, look-alike cyclandelate capsules was considered by the Second Circuit, which found:

> Their argument that look-alike capsules reduce patient confusion or anxiety in taking medication enable doctors to communicate with patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry.

638 F.2d at 544.

Furthermore, in reviewing the evidence the Second Circuit noted:

> Indeed one witness called by appellants (Lawler) testified that when the doctor or the druggist explains that the different color or differently shaped capsules are the same generic drug, patients do not refuse to accept and use it. There was no evidence that doctors or druggists refused to furnish such explanations. No patient testified to confusion or anxiety. Nor did appellees offer any survey of the patients' attitudes with respect to the matter.

638 F.2d at 544-545. Petitioners' contention that look-alikes are needed to eliminate patient anxiety and confusion are directly rebutted by those state substitution laws which require man-

datory disclosure of generic substitution. *See e.g.*, Fla. Stat. Ann. § 465.25 (1981); Ky. Rev. Stat. § 217.822 (1980); Vt. Stat. Ann. tit. 18 § 4605 (1980); and Wis. Stat. Ann. § 450.075 (1980). Such laws clearly intend that pharmacists disclose that a generic has been substituted, in direct contradiction of Petitioners' arguments that patients should not discover or be advised that they are receiving a generic substitute.

Furthermore, Petitioners fail to present any indication that patients want to be deceived. Logic dictates that consumers wish to know which medication they are receiving. They can then make an informed decision as to which pharmaceutical product they wish to purchase and that decision may be based on their perception of the reliability of the manufacturer, the relative cost of the products, or whatever other criteria on which they may base their decision. Patients cannot make that decision unless they can distinguish between products. A recent research poll taken by Cambridge (Massachusetts) Reports, Inc. revealed that 90% of the consumers surveyed believed it important to know if a generic substitute had been dispensed. Of those individuals, 25% felt that the use of look-alikes would cause confusion. *America's Health*, Vol. III, No 1, Spring, 1981, at 15.

Petitioners simply have not proved their argument because it is without merit. Patients are better off being informed, not deceived. Consumers are in a stronger position when they are given all the facts rather than having the truth withheld from them. If Petitioners believe that "patient anxiety" should entitle them to delude consumers into believing that generics are actually brand-names, then a logical extension of their argument is that they be allowed to imprint Ives' name and identification number on their capsules.

There is yet another reason why look-alikes may be detrimental to the consumer. Sometimes, fortunately very rarely, a pharmaceutical is improperly manufactured or handled and may become adulterated.

Should such an event occur, accountability and identification become critical factors. Should a drug produce harmful effects, it is vital that the offending product be identified not only so that the injured consumer might have recourse against the manufacturer, but also so that health agencies can identify the pharmaceutical, pin-point its maker and remove it from the market. The existence of a plethora of capsules all identical or nearly identical in appearance, manufactured by different companies, complicates that process, placing the public health at risk.

A similar situation could arise if a product is not effective. Assume a physician prescribed Cyclospasmol and the pharmacist substituted a generic look-alike. Assume that the look-alike was either adulterated or perhaps was not effective. The patient, not knowing he or she had received a substitute, would report that the drug was not working and the physician might well then assume that cyclandelate was not the proper medication. In such a situation, it is important that there be accurate product manufacture identification, so that the consumer and physician are able to distinguish between manufacturers of similar products.

In *SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* the Third Circuit considered this question and the concern it voiced is applicable to this case. The court noted that any patient or physician dissatisfaction would naturally be directed toward the long-standing brand-name manufacturer and that any suit would be filed against the "deep pocket defendant." The Third Circuit wrote:

> the striking similarity in appearance of the two products would make it entirely unlikely [the brand-name company] could prove that the harm was cause instead by [generic] capsules, because the only proof as to the source would be the capsules, long since digested by the patient.

625 F.2d at 1066.

This concern also extends to the consumer. If a patient knows that he purchased only a "blue capsule," he might well not know which manufacturer(s) to sue, particularly if the capsules had long since been digested. Litigants who have been unable to identify the precise manufacturer of an allegedly defective drug have not fared well in court, their cases having been dismissed. *See, e.g. Ryan* v. *Eli Lilly Co.*, 514 F.Supp. 1004 (D.S.C. 1981) and cases cited therein. Thus, this Court can insure that consumers retain the practical right to sue the maker of a defective drug by rejecting Petitioners' contention that they be allowed to market drugs so similar to a pre-existing drug that confusion and deception result.

There is little reason why Petitioners cannot manufacture generic substitutes in capsules different in appearance and color from Respondents. In *Hoffmann-LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc., supra*, the District Court related that two major capsules manufacturers, Elanco Products and Parke-Davis, had, respectively, 40 and 43 different colors available for capsules. Assuming the capsules often come in two colors, the Court calculated that there were 1,600 or 1,849 possible combinations available, 210 U.S.P.Q. at 381. In *Marion Laboratories, Inc.* v. *Michigan Pharmacal Corp.*, 338 F.Supp. 762, 768 (E.D. Mich. 1972), *aff'd mem.*, 473 F.2d 910 (6th Cir. 1973), the court noted that there appeared to be as many as 12,000 color combinations available. Surely one or more of those combinations might be used by Petitioners.

D. The Only Acceptable, Effective Method To Ensure That Patients/Consumers Are Well Informed About Generic Substitutes Is To Require That They Are Visually Distinguishable.

Various parties before the Court in this case have suggested a variety of means by which the consumer might be informed that a generic substitute has been dispensed. Implicit in these suggestions is a recognition that consumers must be informed and that competing drug products must be clearly distinguishable from each other.

Petitioner Premo suggests that, at most, the manufacturers or distributors of generic substitutes be required to label bottles containing their products in such a way that pharmacists purchasing them are warned not to dispense them in violation of state substitution laws and not to mislabel them as Cyclospasmol, Brief at 33. Such a suggestion is virtually meaningless. The District Court opinion below, *Ives Laboratories Inc.* v. *Darby Drug Co., Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980), commented that such a requirement "would not be useful" because pharmacists are already aware of the difference between the brand name product and the generic substitute, 488 F.Supp. at 398. Any pharmacist who violates a state substitution law will do so regardless of such labels. It is still the consumer who needs to be informed, not the pharmacist.

The State of New York, as Amicus Curiae, offers a different alternative. The State suggests that generic substitutes be required to contain a logo or imprint in a contrasting color so as to be readily visible, Brief at 7. This possibility was considered and rejected by the District Court, *supra*, and by the Third Circuit in *SKF* v. *Premo Laboratories, Inc., supra*. This fine print goes unnoticed by most consumers and those with poor eyesight are unable to even read it. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc.*, the Third Circuit noted that such identification is "decipherable only with great difficulty," 625 F.2d at 1061. The District Court originally hearing this case also considered this question and concluded "nor would it be fruitful to require all defendants to print their names on the capsules. The evidence showed that the capsules are so small that such an imprint would be of little, if any, value," 488 F.Supp. at 398. Consumers are thus best informed that products are different when they have distinct differences in appearance, such as color, size, or shape, and not when they have only the minor variations caused by tiny type face.

The United States, as Amicus Curiae, suggests another possibility — that generic manufacturers prepackage their products

with their own labels for resale to consumers. Thus, the pharmacist would not rebottle or repackage the product. While this idea has some merit in that it would help identify the product involved, it presents significant practical problems. The number of pills to be dispensed in any given prescription varies widely. Thus to comply with this requirement a pharmacist would have to have on hand, for example, prepackaged bottles containing, respectively, 10 capsules of each generic, 15 capsules of each generic, 20 capsules of each generic, 25 capsules of each generic, and so on. Such a requirement would be unworkable and would be detrimental to the patient. Pharmacists buy in bulk and then rebottle. It would be more costly to purchase prepackaged bottles and this increased cost would ultimately be borne by the consumer. Furthermore, logistical problems of stocking the large number of prepackaged bottles might deter pharmacists from carrying generics, thus lessening the options available to the consumer.

None of these proposed solutions are adequate to remedy the core issue of providing patient/consumers with full disclosure to enable them to realize savings from substituted generics and to protect their health and welfare through informed consent. In fact, the only effective means available to protect the patient/consumer demands that the competing drug products be unambiguously distinguishable by color, shape, and size.[4]

There is a dramatic need for easily recognizable, distinguishing characteristics to differentiate generics from the brand-name products. If a patient has been purchasing, for example, pale blue capsules of a given size for a particular condition, he

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[4] Amicus Curiae notes with approval the recent resolution adopted by the Board of Directors of the Health Insurance Association of America. In its 1 November, 1981, Position Statement on Generic Drugs the Directors resolved that "The HIAA opposes any practice with respect to the manufacturing and dispensing of drugs which could lead to confusion or deception of consumers."

will be alerted that a generic is being substituted if he receives dark green capsules of a different shape the next time the prescription is filled. The difference in color, size, and shape serves to notify the patient that a change has occurred. The consumer may wish to request that the brand-name be dispensed or the consumer may wish to comparison shop to determine which pharmacist offers the best price savings for the generic substitute. By the use of visually distinguishable substitutes, it is the consumer who makes the choice, not the manufacturer or the pharmacist.

Petitioners' argument that economic necessity forces them to copy, confuse and deceive should fall upon deaf ears. Many generic producers manufacture their products in capsules totally dissimilar from the pre-existing brand-name pharmaceutical. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* the Third Circuit found that while many generic companies produce look-alikes, an equal number market products that are not similar to the brand-names, 625 F.2d at 1060, n.3. In the opinion below, the Second Circuit noted that many generic drugs are successfully marketed without copying other products and cited the generic cyclandelate manufactured by the W. E. Hauck Company as an example, 638 F.2d at 545. In fact, the competitive system engendered by the substitution laws ensures that generics are given every advantage to compete. The resort to consumer deception, under the rubric of competition, is unsupportable and must not be allowed to override the much more substantial interest of patient/consumers to be well informed and to realize the cost savings from generic substitutions. *Pharmaceutical Society of the State of New York* v. *Lefkowitz,* 586, F.2d 953 (2nd Cir. 1978).

V. CONCLUSION

The core of Petitioners' case is that they should be allowed to practice deception. They admit that they deliberately attempt to confuse the American public. They argue that patients are really

better off not knowing what drug they are paying for and that look-alike substitutes actually perform a public service by deluding consumers.

Such arguments are nonsense and should be rejected out of hand. Patients have the right to know what choices are available to them and have the right to make informed decisions. As this Court succinctly said in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra*, "people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them," 425 U.S. at 770.

For the foregoing reasons, Medicine in the Public Interest respectfully requests that this Court uphold the decision of the United States Court of Appeals for the Second Circuit.

Respectfully Submitted,

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